

REMARKS

I. Amendments to the Claims:

Claims 1-34, 36-43, 45-63, 65-67, 69-74, 76-78, 81, and 83-88 are pending and under examination in this application.

Claims 34, 43, 47-48, 52, 58-59, 63, 67, 74, 81, 84, and 86 have been withdrawn as directed to a non-elected invention.

Claims 3, 56-59, 65-67, 69, 72-74, 76-78, and 85 have been canceled herein without prejudice. Applicant reserves the right to pursue the subject matter of these claims in a continuing application.

Claims 1, 2, 10, 16-19, 27, 70, and 83 have been amended herein. Support for the claim amendments can be found in the original claims and throughout the application as filed. Accordingly, no new matter has been added by way of the instant amendments.

Upon entry of the instant amendment, claims 1-2, 4-33, 36-42, 45-46, 49-51, 53-55, 60-62, 70-71, 83, and 87-88 will be pending and under examination in this application.

II. Priority:

The Office Action required certified copies of the PP 9778, PR 0745, PCT/AU00/00329, and PCT/AU01/01291 pursuant to 35 U.S.C. § 119(b) (*see*, Office Action, page 3). Certified copies of the PP 9778, PR 0745 applications are attached with this Amendment as **Appendix A** and **B**, respectively. With respect to the two PCT applications, Applicant notes that the PCT applications, and any amendments, are published by WIPO. Accordingly, it is unclear why the those documents published by WIPO, and which are publicly available are insufficient for purposes of 35 U.S.C. § 119(b).

III. Claim Objections:

The Office Action objected to claim 1 because of the use of the abbreviation "HSC" without it being spelled out at the first occurrence of the term (*see*, Office Action, page 4).

Claim 1 has been amended herein to spell out "HSC". Accordingly, the grounds for this objection have been overcome.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement:

Claims 1, 8-9, 10, 19-26, 27, 55, 56-57, 65-66, 69-71, 72-73, 76-78, and 85 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabling (*see*, Office Action, page 4).

The Office Action noted that the specification was enabling for:

"A method for reducing or lowering HIV viral titer or infection in new cells in a patient comprising: ablating T cells of the patient; reactivating the thymus of the patient; genetically modifying cells in vitro with a vector construct encoding and expressing a gene product that inhibits replication of human immunodeficiency virus."

Without acquiescing to this rejection and solely to expedite prosecution, Applicant has amended claims 10, 19, and 27 herein, in line with the language suggested by the Examiner as being enabled. In view of the instant amendment, Applicant respectfully submits that the rejection of claims 1, 8-9, 10, 19-26, 27, 55, 56-57, 65-66, 69-71, 72-73, 76-78, and 85 under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

V. Rejections Under 35 U.S.C. § 112, Second Paragraph:

Claims 1-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite (*see*, Office Action, pages 8-9). More specifically:

(a) Claim 1 was rejected for lack of antecedent basis for the recitation "the patient" in lines 3-4 of the claim.

Applicant has amended claim 1 to provide antecedent basis for "the patient." Accordingly, the grounds for this rejection of claim 1, and the claims depending therefrom, have been obviated.

(b) Claim 16 was rejected for lack of antecedent basis for the recitation "the method of disrupting sex steroid signaling to the thymus."

Applicant has amended claim 1 to provide antecedent basis for this phrase. Accordingly, the grounds for this rejection of claim 16, which depends on claim 1, has been obviated.

(c) Claim 17 was rejected for lack of antecedent basis for the recitation "the pharmaceuticals."

Claim 17 has been amended to depend from claim 16 which provides antecedent basis for the terms at issue. Accordingly, the grounds for this rejection of claim 17 has been obviated.

(d) Claim 18 was rejected for lack of antecedent basis for the recitation "the LHRH agonists."

Claim 18 has been amended to depend from claim 17 which provides antecedent basis for the terms at issue. Accordingly, the grounds for this rejection of claim 18 has been obviated.

VI. Rejections Under 35 U.S.C. § 102(b):

Claims 1-9, 12, 14-15, 27-33, 36-40, 53-55, 60, 83, and 88 are rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Sykes *et al.* (U.S. Pat. No. 5,658,564) as evidenced by Frederickson *et al.* (Developmental and Comparative Immunology, 18:251-263, 1994) (*see*, Office Action, pages 9-12).

For a reference to anticipate a claimed invention in terms of 35 U.S.C. § 102, the prior art must teach *each and every element* of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

This rejection is directed at three of independent claims under examination in the instant application: claims 1, 27, and 83, and the claims depending therefrom. All three of the independent claims, as amended, include a step of reactivating the thymus of the patient by disruption of sex steroid mediated signaling to the thymus of the patient.

Sykes, either alone, or in view of Frederickson, fails to teach or suggest this feature. Because Sykes fails to teach each and every element of Applicant's claims it fails to anticipate these claims.

Accordingly, in view of the instant amendments to the claims, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 102(b) of independent claims 1, 27 and 83. Likewise, the rejection of dependent claims 2, 4-9, 12, 14-15, 28-33, 36-40, 53-55, 60, 83, and 88 which contain all the limitations of independent claims 1, 27, and 83, as amended, should be reconsidered and withdrawn.

VII. Rejections Under 35 U.S.C. § 103(a):

(a) Claims 1, 16-19, 22-27, 41-42, 45-46, 49-51, and 87 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sykes *et al.* (U.S. 5,658,564) in view of Nowak (New Scientist 19/26, page 11, January 2, 1999), Garzetti *et al.* (Obstet. Gynecol. 88:234-240, 1996), and Mathias (U.S. 5,434,136). (*see*, Office Action, page 12).

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), the Office Action must establish that: (i) the combination of references discloses all the elements of the claim; (ii) there is “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does . . .” *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731 (2007); and (iii) there is a reasonable likelihood of success.

Applicant respectfully submits that the combined references do not render Applicant’s claimed invention for the reasons detailed below.

Independent claim 1 as amended is directed to a method for genetically altering a patient whose thymus has been at least in part deactivated, comprising the steps of genetically modifying cells selected from the group consisting of hematopoietic stem cells (HSC), lymphoid progenitor cells, myeloid progenitor cells, epithelial stem cells and combinations thereof, and delivering them to the patient while the patient’s thymus is undergoing reactivation by disruption of sex steroid-mediated signaling to the patient’s thymus.

Independent claim 19 as amended is directed to a method for reducing or lowering HIV viral titer or infection of new cells in a patient, wherein the patient’s thymus has been at least in part deactivated, comprising the steps of ablating the patient’s T cells; reactivating the thymus of the patient by disrupting sex steroid-mediated signaling to the thymus of the patient; and

administering genetically modified cells to the patient, wherein the genetically modified cells are selected from genetically modified HSC, lymphoid progenitor cells, myeloid progenitor cells, and combinations thereof, and wherein the cells are genetically modified *in vitro* with a vector construct encoding and expressing a gene product that inhibits replication of human immunodeficiency virus (HIV).

Independent claim 27 as amended is directed to a method for genetically altering a patient whose thymus has been at least in part deactivated, comprising reactivating the thymus of the patient by disrupting sex steroid-mediated signaling to the patient's thymus; genetically modifying cells *in vitro* with a vector construct encoding and expressing a gene product that inhibits replication of human immunodeficiency virus (HIV); and administering the genetically modified cells to the patient; wherein the cells are selected from the group consisting of stem cells, progenitor cells, and combinations thereof.

Applicant notes that claims 2-7, 10, 12, 14, 15, 20-21, 28-33, 36-40, 53, 54, 60, and 80 have not been rejected. Thus, importing the limitations of any of these claims into the independent claims should render the amended independent claims, and the claims depending therefrom, non-obvious. Here, Applicant has amended independent claims 1, 19, and 27 to include the limitation of non-rejected claim 3 (*i.e.*, "whose thymus has been at least in part deactivated"). Accordingly, Applicant avers that independent claims 1, 19, and 27 as amended, and the claims depending therefrom, are non-obvious over the combined references. Thus, Applicant respectfully requests that this rejection under § 103(a) be reconsidered and withdrawn.

(b) Claims 1, 8-9, 11, 13, 27, 55-57, 69-73, 76-78, and 85 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sykes *et al.* (U.S. 5,658,564) in view of Nowak (New Scientist 19/26, page 11, January 2, 1999), Garzetti *et al.* (*Obstet. Gynecol.* 88:234-240, 1996), and Mathias (U.S. 5,434,136), and further in view of Dropulic *et al.* (U.S. 6,232,120). (*see*, Office Action, page 16).

Applicant notes that the Office Action has not rejected claims 2-7, 10, 12, 14, 15, 20-21, 28-33, 36-40, 53, 54, 60, and 80. Thus, importing the limitations of any of these claims into the

independent claims should render the amended independent claims and the claims depending therefrom non-obvious. Here, Applicant has amended independent claims 1 and 27 to include the limitation of non-rejected claim 3 (*i.e.*, "whose thymus has been at least in part deactivated"). Accordingly, independent claims 1 and 27 as amended, and the claims depending therefrom, are non-obvious over the combined references. Thus, Applicant respectfully requests that this rejection under § 103(a) be reconsidered and withdrawn.

(c) Claims 27 and 61-62 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sykes *et al.* (U.S. 5,658,564) in view of Bolotin *et al.* (*Blood*, 88:1887-1894, 1996) (*see*, Office Action, page 18).

Applicant notes that claims 2-7, 10, 12, 14, 15, 20-21, 28-33, 36-40, 53, 54, 60, and 80 were not rejected in the Office Action. Thus, importing the limitations of any of these claims into the independent claims should render the amended independent claims and the claims depending therefrom non-obvious. Here, Applicant has amended independent claim 27 to include the limitation of non-rejected claim 3 (*i.e.*, "whose thymus has been at least in part deactivated"). Accordingly, Applicant avers that independent claim 27 as amended, and the claims depending therefrom, are non-obvious over the combined references. Thus, Applicant respectfully requests that this rejection under § 103(a) be reconsidered and withdrawn.

VIII. Double Patenting:

Claims 1-5, 7, 14-19, 22-33, 36-37, 39-42, 45-46, 49-51, 60-62, 83, and 87-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 19-20, 23, 25, 28-31, 34-36, 36-40, 55, 57-60, 62, 64-65 of co-pending U.S. Appl. No. 10/749,119 and over claims 29-33, 36-42, 45-50, 80-82, 9-98 of co-pending U.S. Appl. No. 10/749,118 (*see*, Office Action, page 20-22).

The currently amended claims of the instant application are generally directed to methods for genetically altering a patient having a T cell disorder caused by HIV infection, to methods for reducing or lowering HIV viral titer or infection of new cells in a patient, and to

methods for improving uptake by the thymus of a patient of genetically modified cells or exogenous cells.

Claims 19-26, 28-40, 55-66, 69-72, and 74-75 of U.S. Appl. 10/749,119 are directed to methods for increasing tolerance in a patient to a graft from an MHC-mismatched donor. These claims do not in any way teach, suggest, or motivate one of ordinary skill to arrive at the currently amended claims of the instant application which are directed to a method for genetically altering a patient having a T cell disorder caused by HIV infection or reducing or lowering HIV viral titer or infection of new cells in a patient.

Claims 29-33, 36-42, 45-50, 80-82, 9-98 of co-pending U.S. Appl. No. 10/749,118 are generally directed to methods for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease and methods for reducing the risk of developing an autoimmune disease in a patient at risk of having or suffering an autoimmune disease. These claims do not in any way teach, suggest, or motivate one of ordinary skill to arrive at the currently amended claims of the instant application which are directed to a method for genetically altering a patient having a T cell disorder caused by HIV infection or reducing or lowering HIV viral titer or infection of new cells in a patient.

Applicant respectfully submits that the preamble of the instant claims is to be given effect. "If . . . the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). When that is properly done here, it is clear that one of ordinary skill in the art would have no reason to consider pursuing the steps of U.S. Appl. Nos. 10/749,118 and 10/749,119 in methods for genetically altering a patient having a T cell disorder caused by HIV infection or methods for reducing or lowering HIV viral titer or infection of new cells in a patient. The mere fact that the steps recited in the two applications may be similar in no way renders the instant claims obvious. Similar steps may be practiced to accomplish completely non-obvious outcomes as in this case.

Accordingly, Applicant respectfully requests that this rejection under the judicially created doctrine of obviousness type double patenting be reconsidered and withdrawn.

CONCLUSION

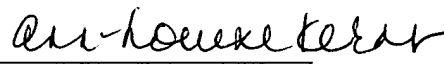
Upon entry of the instant amendments to the claims, claims 1-2, 4-33, 36-42, 45-46, 49-51, 53-55, 60-62, 70-71, 83, and 87-88 will be pending and under examination in this application. Applicant avers that the claims are in condition for allowance and respectfully requests that a Notice of Allowance be issued.

Applicant petitions for a two-month extension of time to respond to the outstanding Office Action. Please charge the requisite payment to our Deposit Account No. 08-0219. Other than these fees no additional fees are believed to be due in connection with this correspondence; however, if any fees are due, or overpayments to be credited please charge the requisite payment or credit the overpayment to our Deposit Account No. 08-0219.

If a telephonic interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: June 16, 2008


Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6192
Fax: (617) 526-5000

APPENDIX A

Attached is a copy of priority application, PP 9778.